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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/089,894 06/03/98 BOMSHTEYN A 19603/871 (CR) VB

HM12/1128

MICHAEL L. GOLDMAN
NIXON PEABODY LLP
CLINTON SQUARE, P.O. BOX 31051
ROCHESTER, NY 14603

EXAMINER

LUKTON, D

ART UNIT

PAPER NUMBER

1653

15

DATE MAILED:

11/28/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/089,894

Applicant(s)

Bomshyeyn

Examiner

David Lukton

Group Art Unit

1653



☒ Responsive to communication(s) filed on Aug 16, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-47 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-47 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8/16/00

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Pursuant to the directives of paper No. 13 (filed 8/16/00), claims 48-51 have been cancelled. Claims 1-47 remain pending.

Applicants' arguments filed 8/16/00 have been considered and found persuasive.

*

35 U.S.C §101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1-11 are rejected under 35 USC §101 because the claimed invention is not supported by an asserted utility.

Claims 1-11 are drawn to betulinol diethers, and a method of preparing such. However, it is not apparent what the asserted utility is for the compounds of claim 1. Applicants are requested to point out the page and line number where the assertion may be found.

Claims 1-11 are also rejected under 35 USC §112 first paragraph. Specifically, since the claimed invention is not supported by an asserted utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have shown anticancer activity for betulinol diacetate and betulonic aldehyde. However, no activity or use for the compounds of claim 1 has been demonstrated. It is also not apparent, as indicated above, what activity is even asserted for the compounds of claim 1. Thus, in the absence of any assertions, guidance or evidence, a skilled chemist would not know how to use the compounds of claim 1.

The remaining claims are drawn to peptide and antibody conjugates of betulinol, or to methods of preparing such. However, while it is true that anticancer activity has been shown for for betulinol diacetate and betulonic aldehyde, it does not follow therefrom that peptide and antibody conjugates of betulinol will exhibit any particular activity. One of the issues is whether any of the conjugates *per se* have anticancer activity, or alternatively, whether betulinol (or an active derivative thereof) is released *in vivo*. There is no evidence of either. Even if cleavage of the bond between betulinol and the peptide (or protein) can occur, there would remain the issues of proper anatomical localization, and further metabolism (e.g., by P-450) of the betulinol derivative to an inactive compound.

Even undue experimentation would provide no assurance that an active compound would be released from the conjugate.

A matter unrelated to the foregoing is that of the synthesis of a diether. The specification does not explain how to produce a diether. If e.g., acetonitrile is combined with betulinol, an ether cannot possibly result if a reducing agent is not present. And even if a reducing agent were present, it is still highly unlikely that an ether could be produced. It may be the case that applicants intended to claim a method of synthesizing a bis-alkanoyl betulinol. Towards resolution of this uncertainty, applicants should at least confirm that the "target" compound of claim 3 contains **no** carbonyl group.

*

Claims 3-6, 13, 15, 25, 26 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite as to the process steps. If an alcohol is reacted with e.g., acetonitrile, an ether will not be formed, regardless of the steps employed. Of course, one could cleave the reaction product to form betulinol, and then alkylate the betulinol itself. However, this would be circuitous at best.

In claims 13 and 15, line 1, clarity would be improved if the term "-peptide-" were placed between quotation marks. See also claims 25 and 26.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'D. Lukton', with a stylized flourish extending from the end.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800